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9 **UNITED STATES DISTRICT COURT**
FOR THE NORTHERN DISTRICT OF ILLINOIS
10 **EASTERN DIVISION**

11 BIDI VAPOR, LLC,

12 Plaintiff,

13 v.

14 VAPERZ LLC, OEM PARTNERS, LLC and
15 VAPERZ ENTERPRISE LLC,

16 Defendants.
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CASE NO.:

**DECLARATION OF AZIM CHOWDHURY
IN SUPPORT OF PLAINTIFF'S
APPLICATION FOR AN ORDER TO
SHOW CAUSE RE PRELIMINARY
INJUNCTION**

DECLARATION OF AZIM CHOWDHURY

I, Azim Chowdhury, of full age, hereby declare as follows:

1. My name is Azim Chowdhury. I am an attorney and Partner with the law firm of Keller and Heckman LLP, located at 1001 G Street NW, Suite 500 West, Washington, D.C. 20001, and represent Plaintiff Bidi Vapor, LLC in U.S. Food and Drug Administration (FDA) regulatory and corporate compliance matters. I submit this declaration in support of Plaintiff's application for an Order to Show Cause for a Preliminary Injunction.

2. My law practice focuses on compliance with FDA statutes and regulations, particularly concentrating on nicotine and electronic nicotine delivery systems (ENDS), tobacco product and cannabis/CBD regulation.

3. The Family Smoking Prevention and Tobacco Control Act (TCA) was adopted on June 22, 2009, and amended the Food, Drug and Cosmetic Act (FDCA) to give FDA authority to regulate the "manufacture, marketing, and distribution of tobacco products." Pub. L. No. 111-31, § 3(1), 123 Stat. 1776 (2009).

4. For purposes of the TCA, the term "tobacco product" is defined to mean, in pertinent part, "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr). FDA was initially charged under the TCA with regulating "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." In addition, it was given authority to regulate in the future "any other tobacco products that [the Agency] by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b).

5. FDA's so-called "Deeming Rule" was published on May 10, 2016 and became effective 90 days later on August 8, 2016. Overall, the Deeming Rule subjects all products that meet the definition of "tobacco product" (except "accessories" of deemed products), including ENDS that contain tobacco-derived ingredients (e.g., nicotine), to virtually all of the TCA's requirements. 81 Fed. Reg. 28,973, 28,975. This includes, among other things, prohibiting the sale of misbranded tobacco products, and imposing advertising restrictions on the sale and distribution of tobacco products. *See* 21 U.S.C. §§ 387c, 387f(d).

1 6. Pursuant to Section 903(a)(1) of the TCA (21 U.S.C. § 387c(a)(1)), a tobacco product is
2 misbranded if, among other things, its labeling (including packaging) is false or misleading in any
3 particular. A tobacco product is also misbranded under Section 903(a)(7)(A) of the TCA (21 U.S.C. §
4 387c(a)(7)(A)) if, in the case of any tobacco product distributed or offered for sale in any State, its
5 advertising is false or misleading in any particular. The misbranding of any tobacco product in interstate
6 commerce, and the introduction or delivery for introduction into interstate commerce of any tobacco
7 product that is misbranded, are prohibited acts, pursuant to Sections 301(a) and (b) of the FDCA (21
8 U.S.C. § 331(a), (b)).

9 7. Inaccurate nicotine content on an ENDS label or advertising would be both false and
10 misleading, and renders a product misbranded. FDA has enforced recall actions against ENDS
11 manufacturers for products that contain nicotine concentrations that are different from that indicated on
12 the label.¹

13 I declare under penalty of perjury under the laws of the United States that the foregoing is true
14 and correct. Executed this 5th day of April 2021 at 1001 G Street N.W., Suite 500W, Washington, D.C.
15 20001.

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19 Azim Chowdhury

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27 ¹ See, e.g., U.S. Food & Drug Admin., Recall Alert: Drip More, LP Voluntarily Recalls Four Lots of Candy King – Worms
28 3 mg 100 mL due to Elevated Nicotine Content (May 31, 2019), (available at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/drip-more-lp-voluntarily-recalls-four-lots-candy-king-worms-3-mg-100-ml-due-elevated-nicotine>).